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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,741	10/06/2000	IB Mendel-Hartvig	10806-128	1595

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EXAMINER
COUNTS, GARY W

ART UNIT	PAPER NUMBER
1641	11

DATE MAILED: 10/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/582,741	MENDEL-HARTVIG ET AL.	
	Examin r	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6 and 11-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6 and 11-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the claims

The amendment filed September 9, 2002 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-19 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because the preamble of the claim does not correlate with the body of the claim. The preamble of the claim implies the use of a lateral flow matrix however, it is not positively recited in the body of the claims nor have the location of the reactants been positively identified. It is unclear what and where the various reactants are located on the matrix. The matrix in the body of the claim is recited in relation to the calibrator. Is the matrix recited in the body of the claim the same as the flow lateral matrix of the preamble and if it is where are the reactants located on or in the matrix or are they on the matrix at all?

Claim 1, lines 18 and 19 "the calibrator and the analyte" is vague and indefinite. It is unclear what the calibrator is. Is it the same as the analyte or is it an analyte analogue or something else?

Claim 1, line 19 "have the ability" is vague and indefinite. Does the calibrator and the analyte biospecifically bind to Reactant* or not? And if so, do they both bind to the Reactant* or does only one of the two bind to the Reactant*.

Claim 1, line 19 "via" is vague and indefinite. It is unclear what the term encompasses.

Claim 11, part (d) is vague and indefinite. It is unclear how all three steps would be done simultaneously.

Claim 15, line 6 "and" is vague and confusing. It is unclear how (i) and (ii) could be done simultaneously. Consider replacing "and" with "or".

Claim 23 is vague and indefinite because it contradicts independent claim 20. Claim 20 recites one or more detection zones downstream of said one ore more calibrator zones. Claim 23 recites a detection zone coinciding with application Reactant* zone. It is unclear how the application zone for the reactant can be in the same position with the detection zone, which is located, downstream of the calibration zone.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 17, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Robinson et al (WO 95/16914).

Robinson et al disclose a method and device for determining an analyte in a sample involving biospecific affinity reactions. Robinson et al disclose the use of calibration zone(s), in which a calibration reagent is immobilized and has biospecific affinity for the analyte of interest or the binding partner of interest (page 15, lines 15-24). Robinson et al also teach the use of ancillary reagents such as analyte analogues and labeled antibodies. Robinson et al also disclose that the specific binding partner can be coupled to or conjugated to the calibrator (see page 17), to form a complex for detection. Robinson et al disclose that the reagents may be antigen/antibody complexes. Robinson et al disclose that the device may be a flow through device such as a lateral flow matrix (page 5, lines 7-22). Robinson et al disclose the use of measurement zones (detection zones). Robinson et al also disclose that multiple measurement zones may be used to simultaneously or sequentially assay for ligands in the same sample to be conducted (page 7, lines 7-15). Robinson et al disclose that the application zone of the sample is upstream of the detection zone and that the detection zone is upstream of the other zones (figure 4). Robinson et al disclose monitoring the sample value and comparing the sample value to one or more calibrators which corresponds to a standard amount of analyte. Robinson et al also disclose incubating the sample with one or more ancillary reagents (page 15, lines 19-33).

3. Claims 20-25 and 27-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Rylatt et al (WO 97/09620).

Rylatt et al disclose a lateral flow permeable medium (matrix) a calibration zone comprising a calibration agent receptor immobilized to the matrix. Rylatt et al disclose

that a labeled calibration agent (Reactant*) Rylatt et al disclose that the labeled calibration agent is diffusibly attached to a support medium which may comprise the lateral flow permeable medium (page 5). Rylatt et al disclose that the labeled calibration agent is transported through a calibrator zone. Rylatt et al disclose the application zone for labeled calibration agent is located upstream of the calibration zone. Rylatt et al disclose a test (detection) zone downstream of the calibration zone (Figures 2,5,8). Rylatt et al also disclose a non-diffusibly attached analyte receptor in the detection zone. Rylatt et al disclose the invention comprises a kit for use in the methods disclosed by Rylatt.

Rylatt et al is silent concerning the kit comprising the labeled calibration agent (Reactant*) and the calibrator as recited in the instant claims. However, it is inherent that the kit comprises the labeled calibration agent and the calibrator for use in the methods disclosed by Rylatt et al.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 6 and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al in view of Rylatt et al (WO 97/09620).

See above for teachings of Rylatt et al.

Robinson et al differ from the instant invention in failing to disclose Reactant* is bound to the calibrator by transporting Reactant* through the calibrator zones. Robinson et al also fail to disclose that the Reactant* has particles as analytically detectable group.

Rylatt et al disclose a lateral flow device which incorporates a labeled specific analyte detection agent (Reactant*) which is transported trough the calibration zones (see also figures 2,5,8). Rylatt et al also disclose that the label can be a particle (page 9). Rylatt et al disclose that the application of the reagent in this manner allows for a test sample which substantially reduces the number of steps required to perform an analyte assay (page 4, lines 22-30).

It would have been obvious to one of ordinary skill in the art to incorporate deposition and transportation of the Reactant* as taught by Rylatt et al into the method of Robinson et al because Rylatt et al shows that the application of the reagent in this manner allows for a test sample which substantially reduces the number of steps required to perform an analyte assay.

6. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al in view of Self et al (US Patent 4,446231).

See above for teachings of Robinson et al.

Robinson et al differ from the instant invention in failing to teach the diagnosis of an autoimmune disease.

Self et al disclose that immunoassays are used for the detection and/or determination of autoimmune diseases. Self et a disclose shows that immunoassays

have a wide application, in both clinical and non-clinical fields and that they are particularly useful in any circumstance where it is necessary to detect and/or determine small or very small amounts of substances.

It would have been obvious to one of ordinary skill in the art to use immunoassays as taught by Self et al for the diagnosis of autoimmune diseases because Self et al that immunoassays are used for the detection and/or determination of autoimmune diseases and that immunoassays have a wide application, in both clinical and non-clinical fields and that they are particularly useful in any circumstance where it is necessary to detect and/or determine small or very small amounts of substances.

7. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rylatt et al in view of Weng et al (US Patent 4,740,468).

See above for teachings of Rylatt et al.

Rylatt et al differ from the instant invention in failing to teach an immobilized reactant that is biospecific to a second reactant which in turn has biospecific affinity to the analyte.

Weng et al disclose the use of a specific binding partner that is biospecific to a second binding partner, which is in turn specific for the analyte (col 2, lines 47-53). Weng et al disclose that is useful for determining the presence of an analyte in a sample suspected of containing the analyte (col 2, lines 39-41) and also allows for the determination of a plurality of analytes in a test solution (col 3, lines 20-27).

It would have been obvious to one of ordinary skill in the art to incorporate the use of an immobilized specific binding partner (reactant) as taught by Weng et al into the device of Rylatt et al because Weng et al shows that this specific binding partner allows for the determination of a plurality of analytes in a test solution

Response to Arguments

Applicant's arguments filed September 9, 2002 have been fully considered but they are not found persuasive.

Applicant argues that the sensor device of Robinson et al provides the reference zone in a flow stream separate from the measurement zone. This is not found persuasive because Robinson et al disclose a flow device comprising a measurement zone (detection zone) and a reference zone (calibration zone) in which a single fluid sample passes through. Robinson et al disclose that the calibrator and biospecific binding partner (Reactant I) form complexes within this sample. By way of applicants own disclosure, page 7, lines 15-20 a process flow is the direction of the flow from a zone of application of sample and/or reactant and towards existing calibrator and detection zones. One skilled in the art will appreciate that a single flow sample flows from an application zone and towards existing calibrator and detection zones (see figure 4). Therefore, the Robinson et al reference clearly discloses a reference zone in the same flow stream as the measurement zone.

Applicant argues that the Robinson et al does not teach or suggest a lateral flow method wherein a calibrator and an analyte have the ability to biospecifcally bind to an analytically detectable reactant (Reactant*) by equivalent binding sites and wherein a

calibrator zone comprises calibrator or binder located in the same process flow as Reactant I in a detection zone. This is not found persuasive because it is unclear what the binding relationship is between the calibrator and the analyte and Robinson et al disclose that the calibration reagent or an ancillary reagent is a specific binding partner for the ligand under assay, a labeled specific binding partner for the ligand under assay is present as an ancillary reagent and a known amount of the ligand under assay precomplexed to its labeled specific binding partner is present as an ancillary reagent (page 17). Therefore it is examiner's position that the Robinson et al reference still reads on the claims as recited.

Applicant argues that the Robinson et al reference does not teach or suggest the advantages provided by the presently claimed methods, wherein the calibration is relevant to a particular sample and the conditions under which the sample is processed through the process flow stream and compensation is enabled for differences between calibrator and sample solution as well as between runs performed at different times and/or at different places. This is not found persuasive because if the disclosure is such as to suggest a modification or combination, such a step may be obvious even if the motivation or suggestion is different from that suggested by applicant.

Applicant argues that the Self et al reference does not teach or suggest a lateral flow method and employing one or more calibration zones, particularly in the same process flow as a detection zone. This is not found persuasive because examiner has not relied upon the Self et al reference for these limitations, but rather for the disclosure

that it is well known in the art to use immunoassays as part of diagnosing autoimmune disease.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
October 4, 2002

LONG V. LE
SUPERVISORY PATENT EXAMINER
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10/16/02